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Response to Representative Schakowsky's Questions for the Record

House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce)
Hearing on "Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System"

October 22, 2019

I. Product Hopping

A. Product hopping is game drug companies play to keep generics off market
B. Product hopping combines two actions:
   1. Reformulating product so generic version can't be substituted and
   2. Encouraging doctors to write prescriptions for reformulated product
   3. * No innovation reason: brand does not *expand* prescription base; just *migrates* base to block generics
C. Harms from both "hard switches" (original drug pulled from market) and "soft switches" (original drug remains)
   1. Greater harms when brand switches before generic enters market
      a) Promotion/marketing more effective in convincing doctors to prescribe reformulated version
D. Product hopping has massive effect on consumers
   1. Most recent (2009) empirical analysis found $28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal[1]
      a) For $1 billion blockbuster drug, consumers pay extra $765 million each year from delayed competition[2]
   2. Consumers unable to afford high prices cut pills in half, not take needed medicines
E. Overlapping terms
   1. *Product hopping* is defined above
   2. *Patent thicketing* refers to the acquisition of numerous patents to cover a single product
   3. *Evergreening* includes either of the above categories, as well as general "life-cycle management"

II. FTC Report: Necessity

A. Need information on frequency (and types) of product hopping, effect on consumers
   1. This information is not collected by FDA, FTC, or other agencies
   2. Given prevalence of drug companies' arguments that product hopping justified by innovation, full array of evidence would be useful
B. Need information on how soft switches can be anticompetitive, particularly since courts have not recognized harms
   1. *Walgreens*: soft switch did not "eliminate" choice but "added" it as "marketplace" determines "superior[ity]"[3]
   2. *Asacol*: soft switch is not a product hop because it leaves "consumer choice intact" and lacks the "key product withdrawal that undergirds a product-hopping claim"[4]
   3. *Namenda*: soft switch allows patients and doctors to "evaluate the products . . . on the merits" while "hard switch crosses the line from persuasion to coercion"[5]
   4. Each of these assertions ignores the "price disconnect" by which a doctor decides the drug to prescribe and a patient/insurer pays for the drug, leaving no single entity to make the price-quality tradeoff
C. FTC has expertise in authoring pharmaceutical reports such as the influential ones addressing settlements (2002) and authorized generics (2011)

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[1] Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).
[2] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (multiple generics take 90% of sales at average 85% discount).
[3] *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).
[4] *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269-70 (D. Mass. 2017).
[5] *New York ex rel. Schneiderman v. Actavis PLC ("Namenda")*, 787 F.3d 638, 654 (2d Cir. 2015).

III. FTC Report: Contents

A. A model for what a report could contain appears in S. 771 § 406 (115th Cong.)
B. Require FTC to submit report to Congress on extent to which
   1. brand/biologic firms engage in product hopping, which includes analysis of
      a) timing of reformulated product's introduction in relation to generic's market entry,
      b) types of changes made in reformulated product,
      c) patents and market exclusivities awarded to reformulated product, and
      d) various forms of product hopping brand/biologic firms employ
   2. brand/biologic firms assess profitability of new drug based on whether introduced before generic entry
   3. product hopping affects consumers (including total estimated annual cost of doctors prescribing reformulated drug instead of generic)
   4. product hopping affects insurance prices and availability (including cost increases and coverage reductions attributable to economic losses described in #3 above)
   5. product hopping affects brand/biologic profits, revenues, unit sales, and prices
   6. product hopping affects generic sales, profits, and prices
   7. brand/biologic firms withdraw[6] original drugs or keep them on the market
      a) This information is not included in S. 771 but is vital given how
         i. soft switches could harm competition but
         ii. courts (*see Walgreens*, *Asacol*, *Namenda*) do not recognize

IV. Conclusion

A. Product hopping presents anticompetitive nuances that are not always acknowledged
B. FTC can use its pharmaceutical expertise to discern and assess product hopping's competitive effects

[6] This category includes discontinuing manufacturing, announcing withdrawal, and adding to the list of discontinued products.